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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/034,985	12/21/2001	Jay M. Short	DIVER1370-8	9024
25225 7590 01/08/2008 MORRISON & FOERSTER LLP 12531 HIGH BLUFF DRIVE SUITE 100 SAN DIEGO, CA 92130-2040			EXAMINER RAMIREZ, DELIA M	
			ART UNIT 1652	PAPER NUMBER
			MAIL DATE 01/08/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/034,985	Applicant(s) SHORT, JAY M.	
	Examiner Delia M. Ramirez	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-28,30,31,33-41,44,46,48-59,64 and 66-78 is/are pending in the application.
 4a) Of the above claim(s) 15-18,59,69,70,77 and 78 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-11,13,19,23-28,30,31,33-40,50-53,56,57,64,67,68,71 and 72 is/are rejected.
- 7) ☒ Claim(s) 12,14,20-22,41,44,46,48,49,54,55,58,66 and 73-76 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>9/5/07;10/11/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

Claims 8-28, 30-31, 33-41, 44, 46, 48-59, 64, 66-78 are pending.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/11/2007 has been entered.

Applicant's amendment of claims 12, 50, 54-56, 58-59, 66-72, and addition of claims 73-78 as submitted in a communication filed on 10/11/2007 are acknowledged.

New claims 77-78 are directed to a non-elected invention (i.e., method claims). New claims 73-76 are directed to the elected invention. This application contains claims 15-18, 59, 69, 70, 77-78 drawn to an invention non-elected without traverse in a communication filed on 2/24/2005. Claims 8-14, 19-28, 30-31, 33-41, 44, 46, 48-58, 64, 66-68, 71-76 are at issue and are being examined herein.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Information Disclosure Statement

1. The information disclosure statements (IDS) submitted on 9/5/2007 and 10/11/2007 are acknowledged. The submissions are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

Claim Objections

2. Claims 54, 55, 58, 66, 73, 74, 75, 76 are objected to due to the recitation of "SEQ ID NO: 1 from nucleotide 1 to 1296...lacking the bases encoding amino acids 1 to 22 of SEQ ID NO:2" and "(ii) SEQ ID

NO: 2 from amino acids 1 to 432 and lacking amino acid residues 1 to 22 of SEQ ID NO: 2". For clarity and consistency, it is suggested the terms be amended to recite, for example, "SEQ ID NO: 1 from nucleotides 67 to 1296" and "(ii) SEQ ID NO: 2 from amino acids 23 to 432". Appropriate correction is required.

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Claims 8-11, 13, 19, 23-28, 30-31, 33-40, 50-53, 56-57, 64, 67-68, 71-72 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Cheng et al. (U.S. Patent No. 5939303 filed on 11/6/1996, issued 8/17/1999; cited in the IDS) in view of Greiner et al. (Archives of Biochemistry and Biophysics 303(1):107-113, 1993; cited in the IDS). This rejection has been discussed at length in the Final action mailed on 1/11/2006, the Non Final action mailed on 10/12/2006, and the Final action mailed on 6/12/2007. It is maintained for the reasons of record and those set forth below.
5. Applicant argues that one of the unmet challenges in the industry before the instant invention was to economically provide sufficient quantities of isolated, synthetic or recombinant forms of the phytase for use in a feed or food composition. Applicant refers to Warden and states that Warden suggested that the active ingredient in the crude *E. coli* preparations used in the chicken feed may or may not be enzymatic in nature. Applicant also refers to (1) Nelson et al. to indicate that before the instant invention, no one had produced sufficient quantities of isolated, synthetic, or recombinant *E. coli* phytase, and (2) Wodzinski et al. in support of the argument that as recently as 1996, experts in the field dismissed bacteria as a source of phytase for use in food or feed because bacterial phytases have a pH optimum which is neutral to alkaline and they are obtained in lower yields. Applicant refers to Wodzinski et al. as providing a detailed account of how difficult and costly it was to develop a fungal phytase. Applicant

submits that Golovan illustrates that even after two and a half years after the priority date of the instant application, the public state of the art was still searching of an appropriate phytase for use in foods or feeds. Applicant argues that by submission of evidence of secondary indicia of non-obviousness, an obviousness rejection can be overcome. Applicant refers to the declaration previously submitted by Dr. Barton where the great commercial success of PHYZYME (*E. coli* phytase) and its advantages over other phytases are discussed. Applicant reiterates that this declaration is evidence of secondary indicia of non-obviousness (commercial success, long felt need and copying) and that the references cited teach away from using the *E. coli* phytase of Greiner in a food/feed composition as claimed.

6. Applicant's arguments have been fully considered but are not deemed persuasive to overcome the instant rejection. With regard to arguments that the claimed invention is not obvious over the teachings of Cheng and Greiner because prior to applicant's invention there was no economical way to provide sufficient quantities of the *E. coli* phytase for use in food/feed compositions, it is noted that recombinant production of proteins was well known in the art even before the publication of Greiner et al. While Greiner et al. do not teach the recombinant production of the *E. coli* phytase, Greiner et al. clearly teach that the P2 phytase isolated by them is the same protein isolated by Dassa et al. in 1982 (J. Biol. Chem. 257, 6669-6676) which was described as a pH 2.5 acid phosphatase (see Abstract of Greiner et al.). Dassa et al. later published the complete nucleotide sequence encoding the *E. coli* pH 2.5 acid phosphatase (appA gene, J. Bacteriol. 172(9):5497-5500, 1990; cited in the IDS of 9/20/2002) and Ostanin et al. (J. Biol. Chem. 267(32):22830-22836; 1992; cited in the IDS of 9/15/2004) further disclosed the recombinant production of the *E. coli* acid phosphatase first disclosed by Dassa et al. (cited as reference 10 by Ostanin et al.) in *E. coli* BL21 using a T7-based promoter (page 22830, right column, first full paragraph; page 22831, left column, Strains and Plasmids). Thus, all the knowledge required to recombinantly produce the *E. coli* phytase was widely available to the skilled artisan several years before the priority date of the instant application. Moreover, even if recombinant production of proteins would

have not been known before the priority date, it is noted that making a crude *E. coli* lysate would have provided the desired phytase as suggested by Warden et al. As previously indicated, the teachings of Warden (also highlighted in applicant's response) clearly suggest the possibility that the dried *E. coli* crude extract in the chicken feed probably contained a phytase which provide the additional phosphorous in the feed (page 730, right column, first full paragraph). Since making recombinant proteins in *E. coli*, is a well known low-cost alternative for the production of recombinant proteins, and making an *E. coli* crude extract would certainly be considered a low cost process, one of skill in the art cannot reasonably conclude that methods to economically provide the *E. coli* phytase of Greiner et al. were not available before the priority date of the instant application.

With regard to the teachings of Nelson et al., the examiner acknowledges that no *E. coli* phytase had been isolated by 1971 (publication year of Nelson et al.). However, an *E. coli* phytase, its enzymatic properties, and its potential use in food/feed were well known in the art at least by 1993 as Greiner et al. disclosed the isolation of an *E. coli* phytase and further discussed the importance of supplying phytases to food/feed in 1993, four years before the priority date of the instant application. The Examiner acknowledges the teachings of Golovan et al., however they are deemed irrelevant to the issue at hand since Golovan et al. do not teach away from using the *E. coli* phytase of Greiner et al. nor do they teach the impossibility of recombinantly producing the phytase. Not only do Golovan et al. teach that the properties of the *E. coli* phytase are attractive for use in food/feed but Golovan et al. also teach that this phytase can be produced recombinantly, which is what was first taught by Ostanin et al. in 1992. With regard to the teachings of Wodzinski et al., it is noted that clearly Wodzinski et al. was unaware of the enzymatic properties of the *E. coli* phytase of Greiner et al., published three years prior to Wodzinski et al. Thus, in 1996, one of skill in the art could have not reasonably conclude that the characterization of Wodzinski et al. regarding bacterial phytases was accurate as it was well known in the art (at least three years prior the publication of the work of Wodzinski et al.) that at least one bacterial phytase could be

produced recombinantly and had a pH optimum which was acidic. With regard to the difficulties discussed by Wodzinski et al. regarding the isolation of a fungal phytase, it is reiterated herein that the historical account provided by Wodzinski et al. refers to a time span of 87 years starting in 1907, many years prior to the development of recombinant DNA techniques and certainly many years prior to the priority date of the instant application. It should be noted that Wodzinski et al. do not teach that with the recombinant DNA techniques available to one of skill in the art in 1996, recombinant production of a phytase would have been considered a formidable task. Therefore, contrary to applicant's assertions, neither Warden, Wodzinski et al., Barton et al., or Golovan et al. are references which teach away from adding the phytase of Greiner et al. to a food/feed composition.

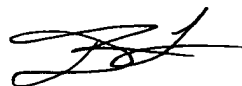
The examiner has previously addressed the declaration by Dr. Barton. The Examiner acknowledges Dr. Barton's declaration as secondary indicia of non-obviousness but as discussed in previous Office actions, the properties which make the *E. coli* phytase of Greiner et al. attractive for use in food/feed were well known in the art before the priority date, the potential use of the *E. coli* phytase of Greiner et al. in food/feed was suggested by Greiner et al., and the recombinant production of the *E. coli* phytase was also well known in the art, as evidenced by Ostanin et al. Furthermore, the teachings of Warden as highlighted by Applicant would have also provided additional motivation to one of ordinary skill in the art to add the phytase of Greiner et al. to animal feed. Thus, for the reasons of record and those extensively discussed above, the claimed invention is deemed obvious over the prior art of record.

Allowable Subject Matter

7. Claims 12, 14, 20-22, 41, 44, 46, 48-49, 54-55, 58, 66, 73-76 appear to be allowable over the prior art of record but are objected to as being dependent upon a rejected base claim and/or the reasons set forth above under Claim Objections.

Conclusion

8. No claim is in condition for allowance.
9. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (571) 272-0938. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (571) 272-0928. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.



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Primary Patent Examiner
Art Unit 1652